

**CLAIMS:**

1. A diagnostic medical instrument adapted to determine whether a patient is suffering from a pre-shock, shock or shock-related condition, the instrument being used in a capillary filling time (CFT) test procedure in which a skin area of the patient overlying blood-filled capillaries normally imparting to the skin a pink color is depressed by a pressure, which is sufficient to expel blood from the capillaries while maintaining normal flow in the veins, said pressure causing the skin to blanch until the skin exhibits a white color, the said pressure being released when a point of maximum blanching is reached to permit blood to flow back to the capillaries at a rate that depends on the condition of the patient to cause the skin to regain its natural pink color; said instrument comprising:
  - I. means including a color sensor trained on the skin area when exposed to light to generate a signal having a magnitude which is a function of light reflected by the skin area whose intensity depends on the natural color of the skin area, wherein the color sensor means includes means to illuminate the skin area with non-modulated light from a light source, and a light reflected therefrom is intercepted by a photodetector which yields a signal that depends on an existing skin color;
  - II. means responsive to said signal before pressure is applied to the skin area to determine its natural pink color to establish a reference base for the test to follow; and
  - III. means responsive to said signal when pressure is applied to said skin during the test to measure the time elapsing from a starting point in time when the depressed skin is at its maximum blanching value of white, and the pressure applied thereon is then released to cause the capillaries to proceed to fill with blood, to a final point in time when the skin recovers its natural pink color as established by the reference base, whereby the CFT measurement is an index to whether the patient is

suffering from a shock-related condition, and to the severity of this condition.

2. An instrument as set forth in claim 1, further including a temperature sensor responsive to heat radiating from the skin area to generate a temperature signal that reflects the existing temperature of the skin area, and means to factor into the CFT measurement the temperature signal to compensate the CFT measurement for the effect of skin temperature thereon.
3. An instrument as in claim 1, wherein the color sensor means includes a video camera responsive to light reflected from the skin area to yield an image signal whose character depends on an existing skin color.
4. An instrument as set forth in claim 1, further including means to apply pressure to said skin area and means to control the magnitude and/or duration of the pressure so as to apply to the skin area the minimum amount of pressure necessary to cause the skin to exhibit a white color.
5. An instrument as in claim 2, in which the temperature sensor is a thermometer placed on the skin area to produce a signal whose magnitude depends on the existing skin temperature.
6. A method for the diagnosis of a shock-related state in a patient by measuring the filling time of blood vessels subjacent to skin area of the patient, comprising the steps of: illuminating the area which is to be gauged for color with a non-modulated light from a light source, filtering out background noises to obtain a base-line measurement, and determining the filling time of blood vessels in said area by comparison of a current color of the area with the base-line measurement.
7. A method according to claim 6, comprising:
  - i) illuminating the area having an original color with non-modulated light from a light source;

- ii) intercepting light reflected from the area with a light sensor, said light sensor producing a first signal having a magnitude which corresponds to the color of said area, said color representing the level of reflection;
  - iii) filtering said first signal for rejecting unwanted signals derived from interfering light, and producing a second signal whose amplitude is proportional to the amplitude of said filtered first signal;
  - iv) storing the amplitude value of said second signal which corresponds to said original color;
  - v) applying a pressure on said area, the magnitude of said pressure and its duration is sufficient to expel blood from said blood vessels to blanch the skin, up to maximum blanching and whitening of said area; and
  - vi) measuring the filling time of blood vessels by rapidly releasing said pressure and subsequently measuring the amplitude of the second signal and displaying the total period of time from maximum whitening at the time of pressure release until the amplitude of said second electrical signal is essentially similar to said stored amplitude value, said total period of time being indicative of a shock-related state in said patient and its severity.
8. A method according to claim 7, further comprising:
- i) sampling the amplitude value of the second electrical signal at a predetermined rate during said measurement and storing said sampled values; and
  - ii) extrapolating the capillary filling time by processing at least a portion of said stored values whenever the rate of change of the capillary filling time remains substantially insensitive to the magnitude and/or duration of the applied pressure.
9. A method according to claim 8, wherein an alert signal is provided whenever the strength and/or duration of the applied pressure be insufficient for obtaining maximum whitening.

10. A method according to claim 7, wherein the pressure is applied and released automatically.
11. A method according to claim 7, further including the step of verification of the measurement by displaying a graphical representation of the measured capillary filling time.
12. A method according to claim 7, further including the steps of:
  - i) repeating the measurement of the capillary filling time at different time intervals;
  - ii) storing the values of all measurements; and
  - iii) displaying a graphical representation of the measured filling times as a function of time, thereby obtaining a derivative of the capillary filling time on time  $d[CFT]/d[t]$ , said derivative being an indication related to the recovery of the patient from an actual or pre-shock state
13. A method according to claim 6, wherein the blood vessels are capillaries.
14. A method according to claim 7, wherein the light is emitted from a LED.
15. A method according to claim 7, wherein the light sensor is a photodetector selected from the group consisting of a photo-diode, a photo-transistor, a photo-resistor and a photoelectric cell.
16. A method according to claim 7, wherein the second electrical signal is produced by integrating the absolute value of the filtered signal.
17. A method according to claim 7, wherein pressure is applied by means of a rigid transducer containing a light source and a light sensor, said transducer being provided with a transparent wall that engages an appendage of the patient, a controlled force being imposed on said rigid transducer toward the surface of said appendage.
18. A method according to claim 17, wherein the applied pressure is controlled by means of a motor arranged to apply a force on said transducer.
19. A method according to claim 17, wherein the applied pressure is controlled by means of an electromagnet applying a force on said transducer.

20. A method according to claim 7, further comprising the step of correcting said amplitude of said second signal to compensate for effects that may be caused by skin movement after said releasing of pressure.
21. Apparatus for the diagnosis of a shock-related state in a patient and of recovery of a patient therefrom comprising:
- i) means for illuminating a skin area of the patient to be gauged for color with a light from a light source, wherein said light is non-modulated;
  - ii) means for filtering out background noises and light to obtain a base-line measurement; and
  - iii) means for comparing the color of the skin area with the base-line measurement, thereby determining the filling time of blood vessels in said area.
22. Apparatus for the diagnosis of a shock-related state in a patient and of recovery of a patient therefrom, comprising:
- i) a light source for illuminating an area of the patient's skin overlying blood vessels, said area having an original color, wherein said light is substantially non-modulated;
  - ii) a light sensor for intercepting light reflected from said area and producing a first signal having a magnitude which corresponds to the color of said area, said color representing the level of reflection from blood vessels subjacent said area;
  - iii) a filter for filtering said first electrical signal and for rejecting unwanted electrical signals originating in interfering light, and for producing a second signal, whose amplitude is proportional to the amplitude of said filtered first signal;
  - iv) means for storing the amplitude value of said second signal which corresponds to said original color;
  - v) a transducer for applying pressure on said area, and for obtaining an amplitude of the second signal which corresponds to maximum whitening of said area;

- vi) a processor for processing data collected by said transducer and for measuring the filling time of blood vessels after releasing said pressure; and
  - vii) means for graphically displaying said processed data.
23. Apparatus according to claim 22, further including means for sampling the amplitude value of the second electrical signal at a predetermined rate during the measurement and for storing said sampled values.
  24. Apparatus according to claim 23, further comprising means for automatically applying and releasing said pressure.
  25. Apparatus according to claim 22, wherein said apparatus is adapted for basing said first signal and said second signal on a portion of said area of skin close to but not including the part of the skin that is directly pressured by said transducer.
  26. Apparatus according to claim 22, further comprising correction means for correcting said amplitude of said second signal to compensate for effects that may be caused by skin movement after said releasing of pressure.
  27. Apparatus according to claim 26, wherein said correction means include a suitable algorithm embodied in said processor.
  28. Apparatus according to claim 26, wherein said transducer comprises means for determining parameters including skin resistance to pressure as a function of depression of the skin responsive to the action of said transducer, and wherein said parameters are provided as inputs to said algorithm.
  29. Apparatus according to claim 22, wherein said apparatus is adapted for maintaining a substantially constant skin-to-light sensor displacement during operation thereof.
  30. Apparatus according to claim 22, further comprising a first temperature sensor for sensing skin temperature of a second skin area close to said first mentioned area, wherein said second skin area is substantially unaffected by heat effects generated by said apparatus.
  31. Apparatus according to claim 30, further comprising a second temperature sensor for sensing skin temperature of said first mentioned area, wherein said

first mentioned skin area is substantially unaffected by heat effects generated by said apparatus.

32. A method for the diagnosis of physiological distress in a patient and for recovery of a patient from a state of physiological distress by measuring the filling time of blood vessels underlying an area of the skin of said patient, comprising the steps of: acquiring an image of skin area to be gauged for color illuminated with a non-modulated light from a light source to obtain a base-line color measurement, and determining the filling time of blood vessels in said area by comparison of the color of at least one more additional images of the gauged skin area with said base-line color measurement.
33. A method according to claim 32, comprising the steps of:
- i) positioning image acquisition means so that an area of the skin lies substantially within the focal plane thereof;
  - ii) illuminating said area having an original color with light radiation from said light source at a level enabling said image acquisition means to discriminate between colors;
  - iii) acquiring an image of said area with said image acquisition means;
  - iv) deriving a signal from said image, said signal representative of the color of the said area;
  - v) storing the value of said signal which corresponding to said original color;
  - vi) applying pressure on said area, said pressure having a magnitude and duration sufficient to expel blood out from said blood vessels, and for obtaining a signal having a value which corresponds to the maximum whitening of said area;
  - vii) measuring the filling time by rapidly releasing said pressure and subsequently measuring and displaying the total period of time from maximum whitening until the value of said signal is substantially the same as said stored value; and
  - viii) determining the physiological distress from said total period of time.

34. A method according to claim 33, wherein the illumination is obtained from background light.
35. A method according to claim 33, further including the step of verification of the measurement by displaying a graphical representation of the measured filling rate.
36. A method according to claim 33, further comprising:
  - i) repeating the measurement of the filling time at different time intervals;
  - ii) storing the values of all measurements; and
  - iii) displaying a graphical representation of the measured filling times as a function of time, thereby obtaining a derivative of the capillary filling time on time  $d[CFT]/d[t]$ , said derivative being an indication related to deterioration in the patient's physiological condition, or to the recovery of the patient from physiological distress.
37. A method according to claim 33, wherein the blood vessels are capillaries.
38. A method according to claim 33, wherein said signal is based on a portion of said area of skin close to but not including the part of the skin that is directly pressured.
39. A method according to claim 33, further comprising the step of correcting said signal to compensate for effects that may be caused by skin movement after said releasing of pressure.
40. A method according to claim 39, wherein said correction is performed using a suitable algorithm.
41. A method according to claim 40, comprising the step of determining parameters including skin resistance to pressure as a function of depression of the skin responsive to the pressing, and providing said parameters as inputs to said algorithm.
42. A method according to claim 33, further comprising the step of measuring a first skin temperature of a second skin area close to said first mentioned area, wherein said second skin area is substantially unaffected by heat effects generated by said apparatus.



43. A method according to claim 42, further comprising the step of measuring a second skin temperature of said first mentioned area, wherein said first mentioned skin area is substantially unaffected by heat effects generated by said apparatus.
44. A method according to claim 43, further including the step of modifying the filling time in step (vii) according to the magnitude of at least one of said first temperature or said second temperature.
45. Apparatus for the diagnosis of physiological distress in a patient and of recovery of a patient from physiological distress in accordance with changes in color of the patient's skin in response to an applied pressure on said skin, said pressure expelling blood from blood vessels subjacent to said skin, said apparatus comprising:
- i) image acquisition means for acquiring an image of an area of the skin of said patient to be gauged for color, said image acquisition means being trained in the area so that it lies essentially within the focal plane of said image acquisition means;
  - ii) means for illuminating the area of the skin to be gauged for color with light radiation at a level sufficient to enable the image acquisition means to discriminate between colors.
  - iii) means for obtaining a base-line color measurement using the acquired image data corresponding to the color of said area when essentially no pressure is applied thereto; and
  - iv) means for comparing the color of said area with the base-line color measurement, thereby determining the filling time of blood vessels in said area after releasing said pressure
46. Apparatus according to claim 45, wherein said illumination means provide modulated light.
47. Apparatus according to claim 45, wherein said illumination means provide non-modulated light.

48. Apparatus according to claim 45, wherein the image acquisition means is a video camera.
49. Apparatus according to claim 45, further comprising a transducer for applying pressure on said area, and for obtaining a signal value, which corresponds to maximum whitening of said area.
50. Apparatus according to claim 45, wherein said apparatus is adapted for basing said color measurements on a portion of said area of skin close to but not including the part of the skin that is directly pressured.
51. Apparatus according to claim 45, further comprising correction means for correcting said color measurements to compensate for effects that may be caused by skin movement after said releasing of pressure.
52. Apparatus according to claim 51, wherein said correction means include a suitable algorithm embodied in said apparatus.
53. Apparatus according to claim 51, further comprising means for determining parameters including skin resistance to pressure as a function of depression of the skin responsive to the pressure action, and wherein said parameters are provided as inputs to said algorithm.
54. Apparatus according to claim 45, wherein said apparatus is adapted for maintaining a substantially constant displacement between the skin and the color measurement means during operation thereof.
55. Apparatus according to claim 45, further comprising a first temperature sensor for sensing skin temperature of a second skin area close to said first mentioned area, wherein said second skin area is substantially unaffected by heat effects generated by said apparatus.
56. Apparatus according to claim 55, further comprising a second temperature sensor for sensing skin temperature of said first mentioned area, wherein said first mentioned skin area is substantially unaffected by heat effects generated by said apparatus.